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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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NEW YORK NY 10112

EXAMINER

KERR, K

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 04/10/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/496,041

Applicant(s)

Takano et al.

Examiner

Kathleen Kerr

Group Art Unit

1652



☒ Responsive to communication(s) filed on 8/23/00

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-19 is/are pending in the application.

Of the above, claim(s) 9-19 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-8 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-19 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5,6,7

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Application Status

1. A preliminary amendment filed was filed on April 13, 2000, which amended claims 1, 7, 9, 10 and 13. Claims 1-19 are pending in the instant application.

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-8, drawn to processes for producing purine nucleotides, classified in class 435, subclass 89.
 - II. Claims 9-19, drawn to DNA and microorganisms, classified in class 435, subclass 252.3
3. The inventions are distinct, each from the other, because of the following reasons:

Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product can be used in a materially different process of using that product, such as for the overproduction of enzymes involved in purine biosynthesis. Thus, Groups I and II are patentably distinct.

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Notice of Possible Rejoinder

4. The Examiner notes that if Group II is found directed to an allowable product, then Group I, which is directed to the process of using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also MPEP 821.04, *In re Ochiai*, and *In re Brouwer*). Since process claims in Group I would be rejoined and fully examined for patentability under 37 CFR 1.104, applicants are instructed to amend said claims as deemed necessary according to rejections made against the elected claims.

Election

5. During a telephone conversation with Mr. Lawrence Perry on August 1, 2000, an oral election was made without traverse to prosecute the invention of Group I, claims 1-8. Affirmation of this election must be made by applicant in responding to this Office action. Claims 9-19 are withdrawn from further consideration by the examiner according to 37 CFR 1.142(b) as being drawn to a non-elected invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Claims 1-8 will be examined in the instant Office action.

Priority

6. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. The priority claim in the instant application is based on a foreign language priority document for which no translation has been provided. Thus, for the purposes of prior art, the U.S. filing date of February 2, 2000 is considered the effective filing date.

Information Disclosure Statement

7. Three (3) information disclosure statements have been filed in the instant application on February 2, 2000, June 13, 2000, and August 23, 2000; all three IDSs have been considered and attached copies are provided.

The IDS filed on February 2, 2000, the Shoichi Takao et al. reference was not considered since said reference is in a foreign language; a translation was filed in the IDS of June 13, 2000 where said reference has been considered. The IDS filed on August 23, 2000 contained a reference whose relevance is questionable, EP 023716. Since the instant reference is in compliance, the Examiner will consider said reference if the relevancy of a patent drawn to electrical connectors is explained.

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Drawings

8. The drawings have been approved by the Draftsmen and are, therefore, entered as formal drawings acceptable for publication upon the identification of allowable subject matter.

Sequence Compliance

9. The sequence listing originally filed in the instant application contained some non-ACSII text at the end of the files. The Scientific and Technical Information Center staff deleted said text, and said sequence listing has been entered for the instant application. No response to this issue is required by Applicants.

10. While the sequence listing originally filed, including paper and computer-readable form copies, is in compliance with the sequence rules, no statement of sameness has been filed. To be in compliance, applicants must provide a statement that the content of the paper and CRF copies filed in the instant application on February 2, 2000 are the same and as required by 37 C.F.R.

1.821(e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d).

Objections to the Specification

11. In the specification, the Abstract is objected to for not completely describing the disclosed subject matter. It is noted that in many databases and in foreign countries, the Abstract is crucial in defining the disclosed subject matter, thus, its completeness is essential. The Examiner

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suggests the inclusion of the enzymes used in the disclosed methods which are GMP synthetase/XMP aminase and inosine-guanosine kinase, the inclusion of *Corynebacterium ammoniagenes* which is a particularly disclosed species useful in the disclosed methods, and the inclusion of IMP, XMP, and GMP which are the common abbreviations of the reagents and/or products of the instant methods.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1 and 5-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "precursor" in claim 1 is indefinite since virtually any compound can be a precursor when pathways to convert the "precursor" into the product are undefined.

13. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The terms "carrying" and "introduced" are not specific terms of art. The Examiner suggests using ---transformed with---. Also in Claim 1, the second paragraph, the enzyme must be clearly linked to using the precursor; for example, insert ---from said precursor--- after "enzyme capable of synthesizing the purine nucleotide from said precursor upon induction".

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14. Claims 3-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The enzyme name "inosine-guanosine kinase or phosphatase" is unclear.

Apparently, the claim language is attempting to read on the forward and backward reaction of kinases; this is clear from the enzyme name ---inosine-guanosine kinase--- without the term "phosphatase".

15. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The terms "acetic acid" and "acetate" are redundant; by the inclusion of both terms, the claim language implies that these are different compounds when this is not the case, as found in the art.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. Claims 7-8 are rejected under 35 U.S.C. 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to processes

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which use expression systems induced by a rise in pH and/or a rise in osmotic pressure; Applicants have described promoters which function via a rise in temperature, P_L promoter, and via acetate, isocitrate lyase promoter. The Examiner notes that Claim 8 is included in this rejection because although it further limits Claim 7 by virtue of the non-sugar used, the other options of pH, temperature, and osmotic pressure are still available to meet the criteria of Claim 8 by virtue of the claim language.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 1-2, 5, and 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Fujio et al. (IDS reference). The instant claims are drawn to methods of making GMP in *Escherichia* using a temperature-sensitive induction expression system of recombinant GMP synthetase.

Fujio et al. teach a method of production of GMP using *E. coli* transformed with a gene for GMP synthetase (XMP aminase) under the control of the temperature-sensitive P_L promoter (see page 842, right column). *E. coli* inherently contain XMP, a precursor; and Fujio et al. teach their method as industrial production of GMP, thus inherently containing a recovery step.

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18. Claims 1 and 3-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Usuda et al. (EP 0816491) (IDS reference). The instant claims are drawn to methods of making GMP or IMP in *Corynebacterium ammoniagenes* using a recombinant expression system of inosine-guanosine kinase.

Usuda et al. teach methods of making IMP and GMP by transforming a host cell, for example *C. ammoniagenes*, with a gene encoding inosine-guanosine kinase (see Example 1).

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Usuda et al. in view of Katsumata et al. (US 5,439,822). The instant claims are drawn to methods of making GMP and IMP in *C. ammoniagenes* using an acetate-induction expression system of recombinant inosine-guanosine kinase.

Usuda et al. teach as described above. Usuda et al. do not teach the use of the isocitrate lyase (ICL) promoter, a promoter useful for acetate induction.

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Katsumata et al. teach the use of the ICL promoter for use in acetate-induction expression systems of recombinant genes (see column 1, lines 59-68).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Usuda et al. and Katsumata et al. to practice the methods of Usuda et al. with the promoter variant taught by Katsumata et al. because Katsumata et al. particularly describe the usefulness of the ICL promoter for efficient expression in coryneform (see column 2, line 5-7).

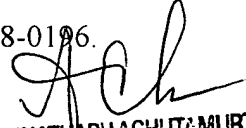
Conclusion

20. Claims 1-8 are not allowed in the instant application for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Kathleen M. Kerr whose telephone number is (703) 305-1229. The Examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Ponnathapura Achutamurthy, can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

KMK
April 9, 2001


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